

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1-54. (canceled)

55. (previously presented) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole or a pharmacologically acceptable derivative thereof at a therapeutically effective concentration for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

56-59 (canceled)

60. (previously presented) The method as claimed in Claim 55 wherein the dose of metronidazole for each application is between from about 125 mg to about 1250 mg.

61-62 (canceled)

63. (previously presented) The method as claimed in Claim 55 wherein the composition is applied between from 2 to 4 times daily.

64. (canceled)

65. (previously presented) The method as claimed in Claim 55 wherein the topical medicament is applied following an anorectal operation.

66. (previously presented) The method according to Claim 65 wherein the anorectal operation is selected from the group consisting of hemorrhoidectomy, a fistulotomy, a fissurectomy, a sphincterotomy, sphincteroplasty and incision and drainage of an abscess.

67. (previously presented) The method according to Claim 65 wherein the anorectal operation is a hemorrhoidectomy.

68. (previously presented) The method as claimed in Claim 55 wherein the concentration of metronidazole in the composition is about 10 wt %.

69. (previously presented) The method as claimed in Claim 55 wherein the vehicle of the composition comprises a mixture of at least two semi-solid saturated hydrocarbon compounds.

70. (previously presented) The method as claimed in Claim 55 wherein the vehicle of the composition comprises white petrolatum (USP).

71. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of at least one steroid.

72. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of at least one analgesic agent.

73. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of at least one antimicrobial agent.

74. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of at least one substance that either promotes skin integrity or inhibits skin breakdown.

75. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of least one anti-inflammatory agent.

76. (previously presented) The method as claimed in Claim 55 wherein the composition further comprises a therapeutically effective amount of at least one antidiarrheal compound.

77. (previously presented) The method as claimed in Claim 76 wherein the antidiarrheal compound is a bismuth salt.

78. (previously presented) The method as claimed in Claim 55 wherein the composition consists essentially of metronidazole at a concentration of about 10 wt % in white petrolatum (USP).

79. (previously presented) A method of treating a patient having Crohn's disease, comprising directly applying to the anorectum and perianal region of the patient a therapeutically effective amount of a composition comprising metronidazole in a concentration of 5 wt% to about 50 wt% of the composition.

80. (Currently Amended) The method as claimed in Claim 79, wherein the metronidazole is in a non-aqueous vehicle.

81. (previously presented) The method as claimed in Claim 80, wherein the metronidazole is in a non-aqueous vehicle selected from the group consisting of petrolatum; zinc oxide; lanolin; a petroleum based-carrier; and a combination of petrolatum ceresin, mineral oil, and lanolin.

82. (new) A method of relieving pain in the treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole at a therapeutically effective concentration for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

83. (new) A method of promoting wound healing following a surgical operation to the anorectum or perianal region in the treatment of Crohn's disease of the anorectum

and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole at a therapeutically effective concentration for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

84. (new) A method of reducing discharge in Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole at a therapeutically effective concentration for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

85. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole in a concentration from about 10 wt % to about 50 wt % for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

86. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole in a concentration of about 10 wt % for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

87. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising

metronidazole in a therapeutically effective concentration as the sole active for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

88. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition consisting essentially of metronidazole in a therapeutically effective concentration for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

89. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole in a concentration of about 10 wt % as the sole active for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle.

90. (new) A method of treatment of Crohn's disease of the anorectum and perianal region comprising applying directly to the affected area a topical composition comprising metronidazole in a concentration of about 10 wt % for the treatment of Crohn's disease of the anorectum and perianal region in a pharmacologically acceptable non-aqueous vehicle, wherein the composition has a fluffy texture.

91. (New) The method according to claim 90, wherein the pharmacologically acceptable non-aqueous vehicle comprises white petrolatum and wherein the fluffy

texture is obtained by passing the white petrolatum and metronidazole through an ointment mill.

92. (New) A method of treating a patient having Crohn's disease of the anorectum and perianal region, comprising:

applying directly to the anorectum and perianal region of the patient an effective amount of a topical composition comprising from about 5 wt% to about 15wt% of metronidazole by weight of the composition in a pharmacologically acceptable non-aqueous vehicle.

93. (New) The method according to claim 92, wherein the pharmacologically acceptable non-aqueous vehicle comprises white petrolatum and the composition is obtained by passing the white petrolatum and metronidazole through an ointment mill.

94. (New) The method as claimed in Claim 93, wherein the topical medicament is applied following an anorectal operation.

95. (New) The method according to Claim 94, wherein the anorectal operation is selected from the group consisting of hemorrhoidectomy, a fistulotomy, a fissurectomy, a sphincterotomy, sphincteroplasty and incision and drainage of an abscess.

96. (New) The method according to Claim 95, wherein the anorectal operation is a hemorrhoidectomy.

97. (New) The method according to Claim 92, wherein the composition is without any additional antibiotic, anti-inflammatory, or immunosuppressive medication.

98. (New) The method according to Claim 96, wherein the composition is without any additional antibiotic, anti-inflammatory, or immunosuppressive medication.